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Bryan Cave LLP 1290 Avenue of the Americas New York, NY 10104			CHANNAVAJJALA, LAKSHMI SARADA	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Receipt of amendment and response dated 8-9-10 is acknowledged.

New claims 36 and 37 have been added. Claims 1, 3-15, 17, 28-31, and 33-37 are currently pending in the instant application.

In response to the arguments, the rejection of claims under 35 USC 112, 2nd paragraph has been withdrawn.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-14, 17 and 28-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over either US 5,968,251 to Auweter (submitted on PTO 1449 of 12-29-08) in view of US 3998753 to Antoshkiw et al or Auweter and EP 937412 ('412) in view of US 3998753 to Antoshkiw et al.

Auweter teaches cold water dispersible powders comprising fat soluble vitamins such as carotenoids prepared by the method described in abstract and col. 2, L 27-46. For the protective colloids, Auweter teaches the claimed proteins such as fish gelatin, vegetable proteins, and also gum such as gum arabic (col. 4, L 40-53). Auweter teaches a 0.5-20% carotenoids and 10-50% by weight of a protective colloid (col. 4, L 53-59). These amounts overlap with the amounts of new claims 36 and 37. For the claimed vitamins of claims 10-11, Auweter teaches carotenoids esters and not the claimed vitamins. Auweter teaches the

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carotenoids powders for food compositions but not tablet preparations (instant claim 17). However, preparing an appropriate form of the composition such as powder or solid tablet or liquid depending on the food preparation would have been within the scope of a skilled artisan. Alternatively, Auweter does not exemplify any compositions with the claimed gums or proteins. Auweter teaches particles of 200 nm size (col. 3, L 51-56) but not the claimed 80 -120 nm.

EP '412 teaches finely divided pulverous carotenoids preparations formed by suspending the active ingredient in an organic solvent, feeding the suspension to a heat exchanger, rapidly mixing with a swellable colloid. EP teaches the particle size such as 213 nm, 225 nm or 400 nm. Among the colloids, EP teaches gelatin, starch, gums, pectin etc (col. 3, L 1-7).

It would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter by incorporating colloids such as polysaccharide gums or proteins such as those taught by Auweter or EP because both references are directed to preparing the claimed powders and further EP suggests colloids such as gelatin and gums as effective in preparing vitamin powder preparations. Further, Auweter suggests preparing the powders with or without an emulsifier and thus meet the claimed matrix claim limitations. Further, EP suggests including carotenoids as well as tocopherol (019) and also suggests particles of less than 400 nm (0009).

Antoshkiw et al (cited in the introduction section of EP reference) US Patent 3,998,753 describes a batch process for the preparation of a water dispersible carotenoid containing powder, wherein the carotenoid has a particle

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size of less than 1 micron, which process comprises (a) forming a solution of a carotenoid and an antioxidant in a volatile solvent, said solvent being selected from the group consisting of halogenated aliphatic hydrocarbons such as chloroform, carbon tetrachloride and methylene chloride; (b) forming an aqueous solution of sodium lauryl sulfate, a water soluble carrier composition such as e.g. gelatin, a preservative and a stabilizer, and adjusting said solution to a pH of about 10 to 11 and (c) forming an emulsion of the solutions of steps (a) and (b) by mixing at a high speed and high shear; removing the organic solvent and spray drying the resulting emulsion to obtain a carotenoid powder. In col. 2, L 16-24, the above reference teaches high optical clarity of the water dispersible powders of carotenoids and further teaches that high speed emulsification employed in the process involves high shear that is essential for obtaining a small particle size (col. 3, L 33-62). The reference also states that the effective shear force is a function of viscosity, solid content, speed of mixing, geometry of mixer and mixing vessel. Furthermore, the reference teaches in order to keep the particle size below 0.1 microns (<100 nm), one has to employ high shear force and high speed mixing.

Thus, a skilled artisan would have been able to prepare the desired particle sizes of carotenoids of Auweter and EP, in particular below 0.1 microns, by optimizing the mixing speed and high shear force such that when dispersed in water the powder results in high optical clarity. Examiner notes that claim 29 recites particle size 80-120 nm, which is within the size range (<400 nm) of EP reference. Thus, applicants have not shown any evidence that one of an ordinary

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skill in the art would not be able to arrive at the claimed particle sizes with the method of Auweter and/or EP.

With respect to the claims 29-35, the claims are directed to a product and not a process. While it is noted that the product claims recite the process limitations, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The examiner notes that the product of claim 29 is no different from the product of claim 1 and hence the process steps do not determine the patentability of the claims.

Claim 15 and 36-37 is rejected under 35 U.S.C. 103(a) as being unpatentable US 5,968,251 to Auweter (submitted on PTO 1449 of 12-29-08) in view of US 3998753 to Antoshkiw et al **OR** Auweter and EP 937412 ('412) in view of US 3998753 to Antoshkiw et al as applied to claims 1, 3-14, 17 and 28-35 above, and further in view of US 3,886,294 to Emodi et al (Emodi, submitted on PTO 1449 of 12-29-08).

Auweter and EP fail to teach the claimed moisture content.

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Emodi also teaches a powder preparation of carotenoids wherein the powder is prepared by mixing fish gelatin with carotenoids crystals and spray drying the resultant solution to form a stable powder of moisture content less than 2% (example 1 in col. 4). Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare the powders of Auweter or Auweter and EP by spray drying where the final moisture content is less than 2% because Emodi suggests stability of the powders. A skilled artisan would have expected the powders of Auweter to be stable.

Response to Arguments

Applicant's arguments 8-29-10 have been fully considered but they are not persuasive.

Applicants argue that rejection did not explain on the record why one skilled in this art would modify the disclosures of Auweter and Antoshkiw or Auweter, Stein, and Antoshkiw in the manner proposed by the Examiner, to arrive at the claimed powder composition. It is argued that the rejection is legally deficient and lacks a motivation and a reasonable expectation of success. Applicants arguments are not persuasive because firstly, all of the cited references are analogous and more over pertinent to the instant claimed invention. The references cited teach particulate powders that include the claimed 80-120 nm. For instance, EP reference teaches particle of less than 400 nm, which includes the claimed range and Applicants have not shown otherwise. Applicants have not provided any evidence that one of an ordinary skill in the art

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would not be able to arrive at the claimed sizes (claims 1 and 32) with the methods of Auweter and /or EP. In paragraph 0026, EP states that the carotenoids and the matrix are mixed, emulsified by a homogenizer to a particle size of 150-400 nm. Thus, EP is not strictly limited to 400 nm and a skilled artisan would have been to try to optimize the particle size to a desired particle size lower than 400 nm size. EP further suggests in [0017] that swellable colloids suitable for matrix include gelatin, gum arabic, milk proteins, and vegetables proteins, a suggestion that one skilled in the art may be able to employ the colloidal materials of EP in Auweter, i.e., gums, starch, gelatine etc., to prepare the dispersible powders of the instant invention.

Applicants' arguments with respect the declarations of Stein and Leuenberger have been addressed in previous action and incorporated herewith. As explained, the declarations of Stein and Leuenberger does not provide any comparative results showing that the particles sizes of less than 400 nm or the claimed sizes are not possible from the disclosures of EP (or Auweter who teaches 200 nm). Applicants argue that Antoshkiw teaches modified emulsification technique and the use of controlled pH in conjunction with sodium lauryl sulfate (SLS) for providing carotenoid particle size of <0.1 micron in the oil phase and the dried powder composition and argues that SLS is a necessary component in the process of Antonshkiw. Applicants argue that as one skilled in the art is aware, SLS is a very hydrophilic detergent surfactant. It is argued that the presently claimed particle sizes are not obtained by the use of a detergent surfactant such as SLS, as disclosed by Antoshkiw; nor are the droplets of the

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claimed powder composition obtained from an emulsion in which a detergent surfactant such as SLS is the emulsifier responsible for the claimed particle size. Contrary thereto, in the disclosed and claimed powder composition of the present application, the solid droplets having an average diameter of about 80 to about 120 nm are dispersed in the matrix consisting of an emulsion-forming composition selected from the group consisting of a natural polysaccharide gum, a mixture of polysaccharide gums a protein, a mixture of proteins, and mixtures thereof. Emulsification using the emulsion-forming composition is used to achieve the claimed powder composition comprising the recited matrix (which consists of the emulsion-forming composition). It is argued that Antonshkiw teaches away from the claimed invention. Applicants further argue that the high amount of SLS taught by Antonshkiw is not desirable in food compositions.

Applicants' detailed arguments have been considered but not found persuasive because Antonshkiw has been cited to show that one skilled in the art would have been able to prepare particles of less than 1 micron from the teachings of EP because the EP recognizes the importance of particle sizes less than 400 nm . While EP does not explicitly state the claimed particle size, EP acknowledges that preparation of less than 100 nm size by way of Antonshkiw reference. Antonshkiw has been further cited for the teachings of high speeds/shear are essential for producing small particle sizes (col. 3, L 33-62). The reference also states that the effective shear force is a function of viscosity, solid content, speed of mixing, geometry of mixer and mixing vessel.

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Furthermore, the reference teaches in order to keep the particle size below 0.1 microns (<100 nm), one has to employ high shear force and high speed mixing.

Thus, a skilled artisan presented with the teachings of EP, Auweter and Antonshkiw would have recognized that the production of vitamin powder compositions of micro and nanoparticle sizes is possible by the methods taught by Auweter, EP as well as Antonshkiw references i.e., with or without SLS.

Therefore, even though applicants argue that instant claims 36 and 37 recite the transitional phrases "consisting" and "consisting essentially", the rejection does not state the use of SLS of Antonshkiw and instead only the high speed taught by Antonshkiw that is important for the production of small particles (nm sizes). In this regard, the Leuenberger declaration of December 2009 (page 6) clearly states that the high speed homogenization is important and further refers to page 21 of the instant specification. The declaration provides the opinion that the particles of Auweter are turbid and not less than 200 nm. However, the example 1 of Auweter state that a clear composition is achieved and thus the compositions are not turbid. With respect to the product-by-process claims, the examiner previously explained that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). The examiner notes that the product

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of claim 29 is no different from the product of claim 1 and hence the process steps do not determine the patentability of the claims.

Applicants' arguments with respect to the teaching of SLS by Antonshkiw particularly in light of the transitional language of new claims 36 and 37 are not persuasive. In response to applicant's argument that instant transitional language does not allow for SLS of Antonshkiw, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicants' argument that there is no requirement in law that applicants prove that the claimed particle sizes are not possible from any of the cited documents is not persuasive because MPEP 2100 states applicant can rebut a presumption of obviousness based on a claimed invention that falls within a prior art range by showing "(1) [t]hat the prior art taught away from the claimed invention...or (2) that there are new and unexpected results relative to the prior art." *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004), 392 F.3d at 1323, 73 USPQ2d at 1229. In the instant application, examiner has provided the rationale as to why one skilled in the art would be able to prepare particles of less 400 nm from the teachings of EP and of Antonshkiw. Once, the examiner provides a prima facie case of obviousness of the instant invention the burden shifts to applicants to rebut the obviousness.

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Applicants' argument that the Declarations have not been rebutted by the examiner is not persuasive because the declarations have been discussed in the previous action. Further, examiner notes that the declaration of Leuenberger refers to the Stein declaration and states that according to Stein one could at best produce particles of 196 nm (para 23 of Leuenberger declaration) and the instant process of producing the particles results in fine particles. However, Example 1 of the instant application also employs high pressure homogenization that is a process known in the art to prepare fine particles (Antonshkiw). Thus, the step of employing high pressure to achieve small particles of less than 100 nm is known in the prior art at the time of the instant invention was made. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Applicants' argument regarding the transparency and clarity of the solutions imparted by instant powder is not persuasive because the dispersions of Auweter (example 1) are also clear upon addition to water. Further, EP '412 also teaches particles that are soluble. Thus, the prior art also teaches clear solutions.

Applicants argue that Examiner did not assert the teachings of Antonshkiw and presents the same arguments made against Antonshkiw. However, the teachings of Antonshkiw and the applicants' arguments regarding Antonshkiw have been addressed in detail above and are incorporated herewith. Emodi has been cited for moisture content and suggests stability of the powders at 2% moisture content. Emodi also teaches optically clear solutions with the stable powders. Thus, the examiner has established a prima facie obviousness for the claimed invention.

Double Patenting

In their response dated 12-7-09, applicants agreed to file a terminal disclaimer upon indicating allowable subject matter. However, at this time no allowable subject matter is indicated. Therefore, the rejection is maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory

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action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM - 5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611